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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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	(PCT Article 36 a	nd Rule 70)	2 ± JAN 2
Applicant's or agent's file reference 28356P WO	FOR FURTHER ACTIO	N See Notifi N Preliminary	cation of Transmittal of Internat Examination Report (Form PCT/IPEA/
International application No. PCT/EP2003/008011	International filing date (de 22 July 2003 (22.		Priority date (day/month/year) 24 July 2002 (24.07.2002)
International Patent Classification (IPC A61K 31/495	c) or national classification and IPC		
Applicant	WILEX A	G	
This report is also acco amended and are the ba 70.16 and Section 607	ompanied by ANNEXES, i.e., sheets confidence of the Administrative Instructions of a total of3 sheets.	ts of the descript ntaining rectific under the PCT).	ion, claims and/or drawings which have ations made before this Authority (see
I Basis of the re			aton and industrial applicability
IV Lack of unity		gard to novelty,	inventive step or industrial applicability
	ments cited its in the international application rvations on the international applic	ation	· .
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Date of submission of the demand	D	ate of completion	of this report
19 September 2003	3 (19.09.2003)	04 N	November 2004 (04.11.2004)
Name and mailing address of the IPE	EA/EP A	uthorized officer	



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/008011

I. Basis	of the report	•
1. With	regard to the elements of the international application:*	
	the international application as originally filed	
$\overline{\boxtimes}$	the description:	
لاجيا	pages 1-29	, as originally filed
	pages	, filed with the demand
\boxtimes	the claims:	
الحا	pages	, as originally filed
	pages, as amended (together v	with any statement under Article 19
	pages	, filed with the demand
	pages 1-26 , filed with the letter of	14 October 2004 (14.10.2004)
\boxtimes	the drawings:	
	pages 1/5-5/5	, as originally filed
	nages	, filed with the demand
	pages, filed with the letter of	
П.	the sequence listing part of the description:	
<u> </u>	pages	as originally filed
	pages	filed with the demand
	pages, filed with the letter of	
the in Thes	regard to the language, all the elements marked above were available or furnished to this atternational application was filed, unless otherwise indicated under this item. e elements were available or furnished to this Authority in the following language the language of a translation furnished for the purposes of international search (under Rule language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary or 55.3). In regard to any nucleotide and/or amino acid sequence disclosed in the international minary examination was carried out on the basis of the sequence listing: contained in the international application in written form. filled together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to been furnished.	which is: e 23.1(b)). examination (under Rule 55.2 and/ onal application, the international go beyond the disclosure in the
in th	The amendments have resulted in the cancellation of: the description, pages the claims, Nos the drawings, sheets/fig This report has been established as if (some of) the amendments had not been made, sin beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).** accement sheets which have been furnished to the receiving Office in response to an invitate its report as "originally filed" and are not annexed to this report since they do not 70.17). replacement sheet containing such amendments must be referred to under item 1 and annexed.	tion under Article 14 are referred to t contain amendments (Rule 70.16

INTERNATIONAL PROLIMINARY EXAMINATION REPORT

national application No.
PCT/EP 03/08011

Reasoned statement under Article 3 citations and explanations supporti	5(2) with regard to novelty, ng such statement	inventive step or industrial applica	ıbility;
Statement			
Novelty (N)	Claims	1-26	YES
	Claims		NO
Inventive step (IS)	Claims	1-26	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO.

Citations and explanations

 The documents are numbered according to the order in which they appear in the search report (D1 to D4).
 Unless otherwise indicated, reference is made to the passages from each document cited in the search report.

2. Novelty (PCT Article 33(2))

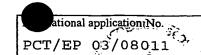
None of the cited documents discloses liposomal formulations with 3-amino- or 3-guanidino-phenylalanine derivatives in a weight proportion of 0.5 to 10%, based on the total weight of the formulation.

Therefore, the subject matter of claim 1 and of dependent claims 2-26 can be considered novel.

3. Inventive Step (PCT Article 33(3))

Document D1 relates to the use of 3-amidinophenylalanine derivatives, including the compound according to the present claim 2 (also known as WX UK1), for treating tumors and metastasis formation. These compounds can also be incorporated into the membranes of liposomes to make it possible to target the active substances (e.g. chemotherapeutics) enclosed in the liposomes (cf. page 14). The tests demonstrating the effectiveness of the substances are carried out with aqueous solutions.

INTERNATIONAL PRESIMINARY EXAMINATION REPORT



The problem to be solved by the present application consists in reducing the undesirable side-effects (such as hemolysis and skin irritation) of aqueous solutions containing phenylalanine derivatives that are administered parenterally.

The solution proposed in the present application is that of providing 3-amino- or 3-guanidino-phenylalanine derivatives in liposomal formulations.

The applicant has demonstrated that liposomal formulations containing WX UK1 result in fewer skin irritations and a reduction in the hemolytic effect compared to aqueous solutions.

Therefore, the subject matter of claims 1-26 can be considered inventive.